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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/751,373 | 12/29/2000 | Donald L. Morton | JWCI:011USC1 | 8298 |

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EXAMINER

SALIMI, ALI REZA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/751,373 | Applicant(s) MORTON, DONALD L. | |
| | Examiner A R Salimi | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-20 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10, 18-20, 32-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment, filed 8/23/04. Claims **1, 7-10, 18-20, 32-33** only are under consideration. Claims 11-17, and 34-36 are withdrawn from consideration as claims are drawn to none-elected Group(s). Applicants are once again requested to cancel the none-elected claims.

Please note any grounds of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant has not addressed the request made by the Office to refer to priority application(s). The request is once again recited. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please also include the patent number.

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 8/23/04.

Applicant argues that in claim 1 allotype is a well known term that describes the antigenic profile of an individual's MHC antigens, and "common allotypes" refer to those allotypes that are more prevalent in a given species. Applicant further asserts that in order to have four allotypes, the composition must contain products from at least four individuals. Applicants conclude that the office's rejection is based on an incorrect factual premise and is improper.

For claim 8 Applicant assert that claim 1 requires only four allotypes, and claim 8 requires that all allotypes to be represented which is more restrictive.

Applicant's argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. Applicant's understanding of the 35 U.S.C. 112, second paragraph is rather misplaced. The claim is indefinite and fails to point out a subject matter which applicant regards as the invention. The claim is directed to a product, and the claim fails to disclose clear boundaries that form the product. Presently, the antigen is not defined, and the MHC profile to the antigen is also not defined. The MHC response is to a small fragment that is being presented in the major cleft of MHC, hence, depending on the fragment that is presented the response would be different regardless of differences in genetic makeup. Since the antigen is not defined and the profile is not defined the claim is vague and indefinite. Moreover, if the allotypes are the same the response would be the same to the same fragment, regardless whether is from one individual or four or ten. Alternatively, if the antigenic fragment that is presented is different

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one from the other, then the responses would not be the same even if the individuals share the same allotypic profile. Still further, the definition of “common allotypes” refer to those allotypes that are more prevalent is confusing, since the claim should define the boundaries and do not allow for varied interpretation to define the claim product. What Applicant may regard as prevalent, someone else might not. Thus, the claim is indefinite because the intended metes and bounds of the composition is not defined. The rejection is maintained.

As for claim 8, the independent claim 1 requires “at least four”, but it could include all, and that is why claim 8 does not further limit claim 1. Moreover Applicant has not addressed the rejection raised fully, the Office had asked for clarification of “all known allotypes”, what the “all known allotypes”? See previous Office Action page 4. Applicants are requested to address this point. The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that Office lacks complete understanding of the invention and the wealth of information provided in the instant specification. Applicant asserts that the present invention derives from the inventors observation that persons immunized with cells from other individuals appear to have an increased ability to fight off viral infections. Enveloped viruses, by definition, will carry allotypes of the individuals in which they were produced. Thus, the inventors determined that

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allotypic antigens on the surface of enveloped viruses could be good targets for the host immune system, but only if that immune system was “primed” against those allotypes-something that does not happen naturally. Applicant asserts that various allotypes were known at the time of filing, and more significantly the use of whole cells as vaccines is described in details. Applicant concludes that the written description is satisfied.

Applicant’s argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. It is rather interesting that Applicant accuses the Office for complete lack of understanding of the invention, and yet at the same time makes the case for the Office. Applicant has only taught the general method, as stated previously by the Office. Applicant’s argument is directed to a method, the same general method Office indicated specification taught and for which Applicant has received patent protection already. First, none of the limitations that Applicant is arguing about is even present in the claimed invention or is even directed to a product, for example, priming has to do with method step and has no bearing on the broad product that is now being claimed which Applicant did not possess. Moreover, observation made is indicative of a method, and not a product. Applicant is requested to carefully read the now claimed invention. Still further, if the wealth of information is not correctly claimed, it would have no value either to the Applicant nor to the Public at large. If the antigenic fragment that induces MHC response is not taught and Applicant did not possess the antigen, then no allotypic profile can be comprised in a product form. It seems Applicant’s understanding of written description is misplaced. In order to practice the invention Applicant must have been in Possession (emphasis added) of the claimed product at the time of invention, in particular given the scope of the now claimed invention. Theoretical wish list does not substitute for actual

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possession of product. Making a broad statement that the genes and protein sequences for many antigens at issue were known is not in proper context. This is an unsupported assertion (emphasis added), some viral genes have been sequenced and their proteins translated. However, this argument is misplaced in at least two fold: One the claimed invention is directed to MHC antigens, not every antigen will be presented via MHC, and those have not been identified. Secondly, the claims are not directed to envelope of any known virus. The claimed invention is directed to MHC antigens that are being presented, whcih includes antigens from cancer, virus, bacteria, fungi, etc...the question is what are these antigens which are representing "at least four common allotypes"? What are their structures? Were they known at the time of filing? Was the Applicant in possession of the antigens? The answer is clearly, NO. These and many other questions like them have to be answered. Applicant was not in possession of the MHC antigens representing at least four common allotypes from a given mammalian species, etc... Profiling allotypes between ethnic and geographic area is vastly different than asserting possession to a product that is now being claimed. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Urban et al (WO 94/04171), for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that present invention requires presence of four distinct allotypes in a single composition. Applicant's argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. First, there is nothing in the claims that says "distinct allotype in a single composition"; hence, the assertion is unsupported. Moreover, as it

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was explained previously the claimed invention is directed to a product and the same or similar product is taught by Urban et al above. Moreover, the burden is on the Applicant to show that the structure taught in the prior art is not capable of performing the intended use. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Moreover, Applicant is reminded that claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In *re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stott et al (WO 93/14126), for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that present invention requires presence of four distinct allotypes in a single composition. Applicant's argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. First, there is nothing in the claims that says "four distinct allotype in a single composition"; hence, the assertion is unsupported. Moreover, as it was explained previously the claimed invention is directed to a product and the same or similar product is taught by Stott et al above. Moreover, the burden is on the Applicant to show that the structure taught in the prior art is not capable of performing the intended use. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant is reminded that claiming a new use, new function or unknown property which is

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inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Irie et al (US patent No. 4,557,931), for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that present invention requires presence of four distinct allotypes in a single composition. Applicant's argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. First, there is nothing in the claims that says "four distinct allotype in a single composition"; hence, the assertion is unsupported. Moreover, as it was explained previously the claimed invention is directed to a product and the same or similar product is taught by Irie et al above. Moreover, the burden is on the Applicant to show that the structure taught in the prior art is not capable of performing the intended use. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant is reminded that claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 1, 7-10, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Pietropaolo et al (US Patent No. 5,891,437) for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that the claims of the cited patent recite a PM-1 protein or epitope thereof, and PM-1 is not an MHC antigen. Applicant's argument as part of

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amendment filed 8/23/04 has been considered fully, but they are not persuasive. First, see claim 5 of the above cited patent which clearly states the antigen is MHC, moreover if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant is reminded that claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ravindranath et al (US Patent No. 6,218,166 B1) for reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant argues that other than claim 19 the compositions described are drawn to a single cell. Applicant's argument as part of amendment filed 8/23/04 has been considered fully, but they are not persuasive. First Applicants are requested to read the claims carefully, Claim 19 indicates combination of all cell types, and applicant is on the record to admit that the cell types are known and available to all. Moreover, the claimed invention is directed to a product and Ravindranath et al above taught the same or similar product. Moreover, the burden is on the Applicant to show that the structure taught in the prior art is not capable of performing the intended use. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, Applicant is reminded that claiming a new use, new function or unknown property which is inherently present in the prior art does not

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necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

9/9/2004

ALI R. SALIMI
PRIMARY EXAMINER